

REMARKS

Reconsideration of the instant application in view of the above amendments and the following remarks is respectfully requested. Claims 42, 44-46, 48-68, and 76-83 are currently pending. Independent claim 42 and dependent claims 44-46, 48-68, and 76-81 stand rejected, while allowable claims 82 and 83 are objected to for depending from rejected claim 42.

By the present amendment, claim 42 is amended to incorporate the features previously recited in allowable claim 82. In light of this amendment, claims 46, 48, 49, 78, and 82 are canceled, and claims 50, 51, 55, and 83 are amended to properly depend from claim 42. Upon entry of this amendment, claims 42, 44, 45, 50-68, 76, 77, 79-81 and 83 will be pending. Support for these amendments may be found throughout the specification and claims as originally filed, and the amendments do not constitute addition of new matter. It should be noted that the above amendments are not to be construed as acquiescence with regard to the Examiner's rejections and are made without prejudice to prosecution of any subject matter removed or modified by this amendment in a related application.

Rejection Under 35 U.S.C. § 112, First Paragraph

Claims 42, 44-46 and 48-81 stand rejected under 35 U.S.C. § 112, first paragraph, for failing to comply with the written description requirement. Specifically, the Examiner asserts that the claimed particles may comprise any of a myriad of cationic, non-cationic, and conjugated lipids, and mixtures thereof, that inhibit aggregation of particles, such that the description and examples provided in the specification fail to provide adequate support for the entire genus of claimed particles. However, the Examiner is of the opinion that claims 82 and 83 satisfy the written description requirement.

Without acquiescence to this basis of rejection, Applicants have amended claim 42 to incorporate the features previously recited in allowable claim 82. Claims 46, 48, 49, and 82 are canceled, and claims 50, 51, 55, and 83 are amended to properly depend from claim 42. Further, claim 78 has been canceled to avoid duplicity with allowable claim 83. Accordingly, all of the pending claims are directed to nucleic acid-lipid particles comprising specific lipids previously recited in allowable claim 82 and, therefore, satisfy the written description

requirement. In light of the above amendments, Applicants respectfully request that the Examiner withdraw this basis of rejection.

With respect to claim 78, the Examiner notes that the instant application provides written description support for the term “dsRNA.” However, the Examiner comments that “[i]n light of the filing date of the priority document [for the instant application], the term ‘dsRNA’ would not have contemplated, and therefore does not encompass siRNA.” (The Examiner does not address this comment to allowable claim 83, which also recites dsRNA). In response to Applicants’ telephone inquiry regarding the basis for this comment, the Examiner explained that siRNA was not discovered until after the filing of the instant application and that, therefore, she does not believe it is proper for the instant claims to cover the mechanism of action of siRNA. Applicants acknowledge that the mechanism of action of siRNA was not known at the time of filing the instant application. However, Applicants disagree with the Examiner’s statement that the instant claims do not cover nucleic acid-lipid particles comprising siRNA, and submit that the instant claims cover nucleic acid-lipid particles comprising any and all nucleic acids.

To this end, the pending claims recite nucleic acid-lipid particles useful for introducing nucleic acids into a cell, and are not directed to the mechanism of action of any such nucleic acid once it has been introduced into the cell. The recited invention provides nucleic acid-lipid particles that are advantageous for nucleic acid delivery, since the nucleic acids are encapsulated in the lipid of the particles and are resistant in aqueous solution to degradation with a nuclease. According to the recited invention, it is understood that this advantage is provided by cationic lipids binding to anionic nucleic acids at the claimed charge ratio of cationic lipid to anionic nucleic acid of 1:1 to 8:1. Thus, the benefits of the recited invention are applicable to any and all nucleic acids, and the instant claims appropriately encompass nucleic acid-lipid particles comprising the same.

Applicants further submit that even though siRNA was not specifically identified and its mechanism of action was not understood at the time the instant application was filed, the claimed nucleic acid-lipid particles include those comprising siRNA. It is well-established that an application need not provide specific support for all species that may fall within a claimed genus, and that claims may cover yet unknown embodiments. *See SRI International v.*

Matsushita Elec. Corp. 775 F.2d 1107 (Fed. Cir. 1985) (*en banc*). Indeed, the Federal Circuit has explicitly stated “[t]hat a specification describes only one embodiment does not require that each claim be limited to that one embodiment,” and “[the law] does not require that an applicant describe in his specification every conceivable and possible future embodiment of his invention.” *Id.* at 1121. Applicants discussed this issue with the Examiner during the telephone conference in the context of chemical compositions, wherein claims to a genus read on all species that fall within the recited genus, including later-identified species that fall within the claimed genus. Of course, this does not necessarily preclude the patenting of such later identified species upon their discovery, thereby providing the inventor of the new species with an opportunity to gain exclusionary rights to his or her invention.

In light of these comments, Applicants respectfully request that the Examiner withdraw her previous comment that claims directed to nucleic acid-lipid particles comprising dsRNA do not cover nucleic acid-lipid particles comprising siRNA, either explicitly or by allowing the instant claims.

Objection to the Claims

Claims 82 and 83, while indicated as being directed to allowable subject matter, stand objected to for depending from a rejected claim. By the present amendment, claim 82 is canceled, and claim 83 is amended to depend from claim 42, which has been amended to incorporate the features previously recited in allowable claim 82, thereby obviating this basis of objection. In light of this amendment, Applicants respectfully request that this objection be withdrawn.

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

In view of the above amendments and remarks, Applicants request that claims 42, 44, 45, 50-68, 76, 77, 79-81 and 83 be passed to allowance. A good faith effort has been made to place this application in condition for allowance. However, should any further issues require

attention, the Examiner is requested to contact the undersigned at (206) 694-4887 to resolve the same.

Respectfully submitted,
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